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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,324	06/29/2001	Bi-Yu Li	1392/18/7/2	8386

7590 09/09/2005

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/896,324	LI ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 0705*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 7, 2005 has been entered.

Status of the Application

2. The action is in response to the RCE filed on July 7, 2005. Currently claims 1-8 are pending. Claims 9-23 are cancelled. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in view of the amendment.

New rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato (USPN.5,707,807) in view of Arbuckle et al. (WO 99/41415).

Kato teaches a method of claim 1 and 4, for amplifying a population of polynucleotides comprising

(a) reverse transcribing an RNA population to provide a double-stranded population (see column 4, lines 11-12);

(b) digesting said cDNA population with one or more restriction endonucleases (see column 4, lines 12-35) having a degenerate recognition ***or*** cleavage sequence, wherein the said restriction endonuclease is a three- to eight-base cutter (see column 7, lines 19-29, which include restriction endonucleases having degenerate bases) and wherein the degenerate recognition ***or*** cleavage sequence is represented by N^m where N is the extent of degeneracy (N is 2-4) and m is number of degenerate bases (m is 1-5) (restriction enzymes) produce different single stranded overhangs for each restriction endonuclease (see column 7, lines 30-35, lines 49-56, wherein cohesive ends are formed with a mixture of A, C, G, and T bases);

(c) ligating said fragments to a series of adaptors lacking restriction endonuclease sites (biotinylated adaptors having degenerate bases), wherein each adaptor is cohesive to all possible overhangs (see column 4, lines 14-21);

(d) amplifying said restriction fragments for 25 to 30 cycles which includes 25 cycles (see column 4, lines 54-61).

With regard to claim 3, Kato teaches said restriction endonuclease comprising four-base cutter (see column 7, lines 19-35);

With regard to claim 5, Kato teaches that the method uses a series of adaptors having a sequence complementary to overhangs (see column 7, lines 49-56);

With regard to claim 6, Kato teaches that said restriction fragments are amplified using PCR to produce PCR products (see column 6, lines 51-60);

With regard to claim 7, Kato teaches that said adaptors provide priming sites for PCR (see column 7, lines 66-67, column 8, lines 16);

With regard to claim 8, Kato teaches that the method comprises detection of PCR products using gel electrophoresis (see column 6, lines 57-60). However, Kato et al. did not specifically amplifying restriction fragments for no more than 25 cycles and quantitation of amplified restriction fragments.

Arbuckle et al. teach a modified AFLP method, wherein Aurbuckle et al. teach that the method comprises primers specific for restriction digestion fragments (see page 12, paragraph 2, line 3-5 under amplification of adapter-modified DNA fragments); use of labeled primers (see page 28, line 12, claim 14, page 15, line 1-2 of paragraph 2 under detection of amplified products, page 16, line 1-2); and detecting and quantifying said amplification products (see page 15, paragraphs 1-2 under detection of amplification products and page 16, line 1-13). Arbuckle et al. also teach amplification using no more than 25 cycles (see page 21, line 18-32).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of detecting polymorphism in AFLP fragments as taught by Kato et al. with a step of including quantitation of amplification products

as taught by Arbuckle et al. for the purpose of enhancing the specificity of detecting a target amplification product to provide an efficient DNA fingerprinting method. One skilled in the art would be motivated to combine the method as taught by Kato et al. with the inclusion quantitation of amplification products and amplification using touchdown PCR with no more than 25 cycles as taught by Arbuckle et al. because Arbuckle et al. explicitly taught that the use touchdown PCR with no more than 25 cycles would solve the problems regarding annealing temperatures of different adapter-primers and aid in specific quantitation of amplified products for the purpose of efficient detection of DNA fingerprinting pattern (see page 15, paragraphs 1-2 under detection of amplification products and page 16, line 1-13). The ordinary artisan would have a reasonable expectation of success that inclusion of inclusion of amplification for no more than 25 cycles and quantitation of the amplified restriction fragments would result in enhancing the specificity of detection of DNA fingerprinting as suggested by Arbucker et al. and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Non-Statutory Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39, 95-98 of copending Application No. 10/055,109 in view of Arbuckle et al. (WO 99/41415). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-8 are drawn to a method of comprising

(a) reverse transcribing an RNA population to provide a double-stranded population;

(b) digesting said cDNA population with one or more restriction endonucleases having a degenerate recognition ***or*** cleavage sequence, wherein the said restriction endonuclease is a three- to eight-base cutter which include restriction endonucleases having degenerate bases) and wherein the degenerate recognition ***or*** cleavage sequence is represented by N^m where N is the extent of degeneracy (N is 2-4) and m is number of degenerate bases (m is 1-5) (restriction enzymes) produce different single stranded overhangs for each restriction endonuclease ;

(c) ligating said fragments to a series of adaptors lacking restriction endonuclease sites (biotinylated adaptors having degenerate bases), wherein each adaptor is cohesive to all possible overhangs;

(d) amplifying said restriction fragments;

Claims 1-8 of the instant invention fall with in the scope of the claims 1, in combination with 6, 10, 14, 16-18, 20 and claim 28 in combination with 29-34, claim 95 in combination with 96-98 because the claims of the co-pending application disclose said method for detecting one or more biological entities in a sample comprising the steps (a) – (d) recited in the instant application. The only variation in the instant invention with that of the co-pending application is

that, the co-pending application does not disclose amplification of restriction fragments for no more than 25 cycles.

Arbuckle et al. teach a modified AFLP method, wherein Aurbuckle et al. teach that the method comprises primers specific for restriction digestion fragments (see page 12, paragraph 2, line 3-5 under amplification of adapter-modified DNA fragments); use of labeled primers (see page 28, line 12, claim 14, page 15, line 1-2 of paragraph 2 under detection of amplified products, page 16, line 1-2); and detecting and quantifying said amplification products (see page 15, paragraphs 1-2 under detection of amplification products and page 16, line 1-13). Arbuckle et al. also teach amplification using no more than 25 cycles (see page 21, line 18-32).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of detecting polymorphism in AFLP fragments as taught by the co-pending application et al. with a step of including amplification for no more than 25 cycles as taught by Arbuckle et al. for the purpose of enhancing the specificity of detecting a target amplification product to provide an efficient DNA fingerprinting method. One skilled in the art would be motivated to combine the method as taught by co-pending application with the inclusion amplification using touchdown PCR with no more than 25 cycles as taught by Arbuckle et al. because Arbuckle et al. explicitly taught that the use touchdown PCR with no more than 25 cycles would solve the problems regarding annealing temperatures of different adapter-primers and aid in specific quantitation of amplified products for the purpose of efficient detection of DNA fingerprinting pattern (see page 15, paragraphs 1-2 under detection of amplification products and page 16, line 1-13). The ordinary artisan would have a reasonable expectation of success that inclusion of amplification for no more than 25 cycles would result in

enhancing the specificity of detection of DNA fingerprinting as suggested by Arbucker et al. and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

This is a provisional obviousness-type double patenting rejection.

Response to arguments:

5. With regard to the rejection made in the previous office action under 35 USC 102(b) as anticipated by Kato et al., Applicants' arguments and amendment are fully considered and found persuasive. The rejection is moot in view of the amendment and new grounds of rejections.

6. With regard to the rejection made in the previous office action under 35 USC 102(e) as anticipated by MacLeod et al., Applicants' arguments and amendment are fully considered and found persuasive. The rejection is moot in view of the amendment and new grounds of rejections.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Patent Examiner
Art Unit 1637

9/5/05